This 17th annual report of the United States Renal Data System is produced by the USRDS Coordinating Center, operated under NIH contract No. DK-9-2343 by the Minneapolis Medical Research Foundation.
The daily lives of ESRD patients are fraught with many complexities and dangers, each of which must first be identified, then evaluated, and finally treated. This year’s annual data report is dedicated to these patients, who face the burden of their disease with dignity and conviction, and to the caregivers who provide counsel, compassion, and expert care and help reduce the strain these patients must endure.

Suggested citation for this report

Publications based upon USRDS data reported here or supplied upon request must include this citation and the following notice:
The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.
The future is a fog that is still hanging out over the sea, a boat that floats home or does not. The trade winds blow me, and I do not know where the land is; the waves fold over each other; they are in love with themselves; sleeping in their own skin; and I float over them and I do not know about tomorrow.
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This is the seventeenth annual report on the end-stage renal disease program in the United States, and the sixth in our atlas series, which provides in-depth graphic presentation of data spanning the last two decades. This ADR also presents information on patients with chronic kidney disease (CKD)—the precursor of ESRD—and assesses care in at-risk populations.

The major focus of this book, however, is the ESRD program, a central public health initiative begun in 1972 with the granting of Medicare coverage to ESRD patients. At its inception, the program was expected to plateau at 40,000 prevalent patients—a number passed more than 20 years ago. ESRD was at first considered a rare disease, as defined by the Orphan Drug Act of 1983 and its subsequent amendments, but that definition also became outdated when the prevalent population exceeded 200,000—the threshold defined by the act—in 1990.

At times during the past 20 years the ESRD program appeared limitless, with incident rates rising 8–14 percent per year. In the late 1990s, however, this growth began to slow, and in the past four years rates appear to have stabilized.

A detailed assessment of incident rates reveals some dramatic progress, with rates in a number of populations returning to levels of a decade ago. Among young whites with diabetes as the primary cause of ESRD, for example, the incidence of ESRD has fallen 47 percent. These findings are not, however, present in young African Americans, a serious concern. Rates of ESRD due to glomerulonephritis have also fallen in both whites and other minorities.

Incident rates in 2003 are more than 10 percent lower than those projected five years ago by the USRDS—a major achievement in public health that merits recognition for efforts by CMS, the CDC, and the NIH, as well as by the renal providers themselves.

In addition, growth in the prevalent population is ahead of projections by 4–5 percent in 2003, suggesting that the death rates anticipated in the original projections have declined.

The ESRD program is, then, approaching the objectives put forth by the Healthy People 2010 program, with reduced rates of ESRD incidence, of incidence due to diabetes, and of mortality due to cardiovascular disease.

These improvements have coincided with the National Kidney Foundation's efforts to establish clinical practice guidelines to help reduce disparities in care. Initial guidelines covered anemia, vascular access, and dialysis adequacy. Subsequent guidelines address bone and mineral disease, cardiovascular disease, lipid disorders, hypertension, and a CKD classification system which defines stages of progressive dysfunction.

Reductions in ESRD, morbidity, and mortality rates during the 1990s occurred as renoprotective therapy was being established with ACE inhibitors and ARBs. The first of these studies, published by Lewis et al. in the New England Journal of Medicine in 1993, established ACE-I therapy for Type I diabetic kidney disease. Subsequent studies (Brenner et al., Lewis et al., Parving et al.) have shown both ACE inhibitors and ARBs to be effective at slowing the rate of loss of kidney function and the development of ESRD across most types of kidney disease. Equally important have been studies on blood pressure control and, more recently, multiple medication interventions (Gaede et al.; DCCT, New Engl J Med 1993; UKPDS, Lancet 1998) to address both kidney disease and high cardiovascular mortality.

Optimism created by these successful clinical trials, however, has been punctuated by neutral and even negative trial results for interventions related to ischemic heart disease (Berl et al.) and anemia treatment (Parfrey et al.), and for dietary interventions with low protein intake.

Information on data requests can be found in appendix B, starting on page 260.
The recent HEMO trial indicated that more dialysis or a high-flux membrane on a three day per week treatment schedule had minimal impact on patient morbidity and mortality (Eknoyan et al.).

But since the early 1990s, incident cohort survival at two, three, four, and five years after initiation has been steadily improving. And in this year’s ADR we show that even prevalent mortality rates in the first year on dialysis—relatively flat over the last 6–7 years—have fallen.

As we demonstrate in the following chapters, there is little doubt that patient care has improved. Dialysis therapy is at an all-time high, as are hemoglobin levels. Following publication of the guidelines, fistula placement rates have doubled over the last nine years. The rate of actual functioning fistulas has grown at a more modest pace, but it too is increasing. And for the first time it appears that use of dialysis catheters, as measured by placement rates, is falling—coinciding with a first-time reduction in hospitalization rates for vascular access infections. Changes in bone and mineral metabolism treatment have also been marked since 2000, something which merits more complete evaluation.

It is thus difficult to reconcile the improving survival rates of dialysis and even transplant patients, along with the quantifiable increase in care that follows clinical practice guidelines, with the lack of efficacy recently noted in trials on dialysis therapy and flux, on the use of statins to reduce cardiovascular events, and on anemia correction to reduce the progression of left ventricular hypertrophy. It may be that other aspects of care have improved. Earlier initiation of dialysis may create a lead-time bias that makes it appear that patients are surviving longer. Improved care in the CKD population may bring to dialysis patients whose comorbidity is better managed. There is little doubt, for instance, that the number of cardiovascular procedures to treat ischemic heart disease has grown, and that survival after these interventions has improved. Or perhaps the consolidation of dialysis providers by the large chains has brought more consistent care.

We are left, then, with the simple observation that mortality is down, patients are living longer, the prevalent population is growing more quickly than anticipated, and there are fewer patients coming to ESRD. Perhaps the magnitude of the disease burden in the CKD and ESRD populations is so large, as demonstrated by the wide range of adverse cardiovascular and infectious events, that classic single-intervention trials are unable to show effects. By all classic standards, the lack of efficacy noted in most ESRD trials on mortality should lead to little or no improvement in overall outcomes of the entire population. The progress, however, is unmistakable, so we must conclude that something is improving in this very complex population.

We must look, finally, at the total breadth of care noted in the ADR and suggested by the clinical practice guidelines. To consider the alternative—that none of the interventions included in the guidelines are effective, as proven by the lack of trial evidence in their favor—would lead us to retreat from the path chosen at the NIH consensus conference in the mid-1990s, when we determined that care needed to be improved. Should we abandon the path, or stay the course and await more evidence on how we are to treat this complex population? It is a dilemma which will be discussed extensively by the entire kidney disease community, as its outcome will determine whether patients ultimately gain, remain at status quo, or, potentially, lose out in the end.

The USRDS was created to monitor trends in ESRD, and now CKD as well. It has reported major milestones in the long history of the ESRD program. We will continue to monitor the care and outcomes of these populations, and, as part of our public mission, to report the results to all stakeholders both in the United States and around the world.

**Additions to the Annual Data Report**

New this year, we examine differences in patient populations and care in urban and rural settings. For these analyses we use the U.S. Census Bureau classification system, in which urban areas are defined as those with core blocks of at least 1,000 people per square mile and with surrounding blocks of at least 500 people per square mile; areas outside of these densely settled blocks are classified as rural. To classify the location of ESRD patients, we use the ZIP code provided on the Medical Evidence form and in the CMS EDB database. The classifications are described at www.census.gov/geo/www/ua/ua_2k.html.

We have also added a new table of contents, immediately after the primary one, pointing to frequently requested data in the Reference Tables.

**Chapter overview**

In the Précis we provide an overview of the ESRD program, beginning with summary statistics on patient counts and rates, modalities, and costs. We look at modality use over time and across the
country, at indicators of quality of care (vascular access use, dialysis therapy, anemia treatment, preventive care, and prescription drug therapy), and at trends in hospitalization and mortality rates. And we examine expenditures—first those related to ESRD, and then those for patients in the Medicare and EGHP populations who have chronic kidney disease.

In the next chapter we address the objectives of the Healthy People 2010 initiative that relate to kidney disease. HP2010 is sponsored by the Department of Health and Human Services in partnership with federal agencies, businesses, communities, and other organizations, and aims to increase life expectancy, advance individuals’ quality of life, and eliminate disparities in health and healthcare. The program sets targets, for example, of lowering the incident rate of ESRD overall and of diabetic ESRD, of increasing fistula use, and ensuring that at least 90 percent of patients receive an influenza vaccination each year. Data in this chapter show progress toward these goals.

Chapter One presents data on individuals with chronic kidney disease, the precursor to ESRD. We look here at the prevalence of CKD across the country, then at the likelihood of patients receiving assessments, preventive care, and prescription drug therapy that could help slow the progression to ESRD. We also look at racial disparities in CKD assessment, at how hospitalization rates in patients with diabetes and congestive heart failure compare in individuals with and without the complicating condition of CKD, and at the associations between a prior history of CKD and outcomes after hospitalization for acute kidney failure.

Trends in the incidence and prevalence of ESRD are presented in Chapter Two, with new comparisons of ESRD rates overall and of diabetic ESRD, of increasing fistula use, and ensuring that at least 90 percent of patients receive an influenza vaccination each year. Data in this chapter show progress toward these goals.

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In Chapter Three we use data from the Medical Evidence form to examine patient characteristics at the start of ESRD therapy. We begin by comparing comorbidities—cardiovascular disease, COPD, and cancer—identified through the ME form and those found through inpatient hospitalizations in the first year of therapy. We also present data on prescription drug therapy in new patients, on anemia at initiation and the use of EPO prior to this time, on biochemical characteristics, and on predictors of the estimated glomerular filtration rate—this year looking at the influence of both body mass index and race on eGFR at initiation.

Chapter Four provides data on modalities and the types of patients using each kind of therapy. Tables present data on incident and prevalent counts and rates, while graphs show patient distribution by insurance coverage, and maps illustrate regional variations in rates over time. The chapter also includes updated data on the probability of death or a change in modality during the first five years of therapy, as well as information on patient distribution by provider.

In Chapter Five we examine progress toward guidelines set by the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (K/DOQI) and toward other targets for clinical care, using data from both patient claims and CMS’s Clinical Performance Measures (CPM) project. We look, for example, at trends in vascular access use and at access events and complications. We also present data on diabetic care and on prescription drug therapy in diabetic patients, and look at the use of preventive care—glycosylated hemoglobin testing, lipid testing, prescription drug use, and vaccinations—in the ESRD population as a whole.

This year Chapter Six, on morbidity and mortality in the ESRD population, has been expanded. We again examine overall and cause-specific hospitalization and mortality; this year, however, we present interval analyses instead of time trends, showing event rates in the first five years of therapy. Analyses of mortality and hospitalization ratios utilize the Bayesian method recently adopted by the USRDS (discussed in the 2004 ADR), and this year include data on mortality from cardiovascular disease and infection, and on hospitalization for cardiovascular disease, infection, and vascular access. We again look at cancer and at pregnancy in women with ESRD, and have added new analyses of morbidity in ESRD, CKD, and non-CKD populations which illustrate dramatic differences among these populations. The three final spreads address new topics as well: withdrawal from dialysis, the use of hospice care, stroke, and dementia.

Chapter Seven addresses the renal transplant population, looking first at transplant rates, waiting times and the number of patients on the wait list, and kidney donation rates. We also examine patient outcomes after transplantation—survival, graft failure, return to dialysis, and preemptive retransplantation—as well as the relative risk of death with function related to both donor and recipient characteristics. A new spread presents data on post-transplant complications and care, including followup care, hospitalization rates, HbA1C and lipid testing, and cancer screening. The chapter concludes with new analyses of the use of immunosuppressive medications, and with expanded analyses of transplant and mortality ratios by provider.

Information on pediatric patients with ESRD is presented in Chapter Eight, in which we first update data on patient characteristics, preventive health care, and vascular access. We examine differences in hemoglobin levels and anemia treatment by age, gender, and race/ethnicity, look at trends in infectious hospitalizations, and present new interval analyses of hospitalization and mortality in children with ESRD. The Cardiovascular Special Studies Center focuses this year’s Chapter Nine on coronary revascularization, looking first at procedure use, mortality, and survival in incident dialysis patients. Analyses of the prevalent population include both ESRD and CKD patients, with data on survival probabilities and mortality rates by age and by diabetic status. Also new this year are analyses of atrial fibrillation (AFIB) in the dialysis population, and of stroke as it occurs with or without accompanying AFIB.

In Chapter Ten, on ESRD providers, we look at anemia management, at the changing nature of providers in terms of profit status and chain affiliation, and at differences in patient characteristics by chain ownership. We also examine compliance with K/DOQI guidelines—including anemia treatment, URR, and vascular access use—and the use of preventive care measures. With DaVita’s acquisition of Gambro in December, 2004, and the acquisition of Renal Care Group by Frese-
Introduction

which allows users to build data tables and maps based on query specifications. The Renal Data Extraction and Referencing System (RenDER) can be accessed on the USRDS website.

To assist users of USRDS data, the Coordinating Center annually updates and revises the Researcher’s Guide, which provides information on all analytical methods used by the CC, along with a detailed index of files and variables in the USRDS researcher datasets. It is available on our website, and a hard copy is sent to researchers who order Standard Analysis Files (SAFs).

**USRDS database**
The Coordinating Center often responds to concerns about changes in reported counts of incident and prevalent patients and in counts by modality. The USRDS dataset is a living record of ESRD care in the United States, and is continually updated with new information on the ESRD population. Delays in the reporting of data are unavoidable, and we add late information to the database as soon as it becomes available. This information includes data from the Medical Evidence form, claims for hospital and physician services, and updates of the Medicare Enrollment Database that are received after the ADR has gone to press.

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**1.3 · Structure of the USRDS database**

![Diagram of the USRDS database structure]

- **USRDS database** (1.6 million patients)
- **USRDS database**
  - **CMS SAF CD**
  - **CMS Part A SAF CD**
  - **CMS Part B SAF CD**
  - **UNOS SAF CD**
  - **CMS EPO data**
  - **CMS facility data**
  - **CDC survey data**
  - **Network SIMS**

**Common Standard Re-usable Working Set Library**

- **ESRD cohort finder files**
- **Patient profile**
- **Modality/payer sequence**
- **Comorbidity profile**
- **Transplant profile**
- **Claims data: Part A, Part B, & EPO**
- **UNOS transplant data**
- **USRDS Special Studies data**

**USRDS Annual Data Report**
**USRDS researcher SAF CDs**
**Data analyses**
**USRDS custom data files**
**USRDS web-based applications**

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**www.usrds.org**

On our website users can download PDF files of the ADR, Excel files of the tables and the data underlying the graphs, and PowerPoint slides of ADR figures and USRDS presentations. Supplemental tables are also included, with standard errors for all rates as well as tables for patient subgroups.

Also available on the website are supplemental tables on ESRD patients covered by Medicare. These tables parallel tables in the printed ADR, and include information on incidence and prevalence, modalities, hospitalization, transplant, mortality, survival, and the costs of ESRD.

**RenDER & the Researcher’s Guide**

We continue to improve our real-time online query system, which allows users to build data tables and maps based on

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**1.6 · Departmental organization of the Special Studies Centers**

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### Administrative oversight

Lawrence Agodoa, MD and Paul Eggers, PhD provide direct oversight of the Coordinating Center and Special Studies Centers, and members of CMS, the ESRD networks, and the renal community provide crucial input and feedback through their committee participation.

The Steering Committee, the governing body of the USRDS, is responsible for the operations of the CC and SSCs. It works under the direction of the Project Officers, and includes representatives from CMS, the NIH, the CC, and each of the SSCs. Its responsibilities include coordination among the centers, study design, project tracking, data management and validation, assurance of data availability for researchers and government officials, and oversight of Annual Data Report production.

The USRDS External Advisory Committee (DAC) includes CMS members, Network Forum representatives, database technical staff, and others appointed by the Project Officers. DAC addresses the
accuracy and completeness of data provided to the USRDS, and works to ensure timely fulfillment of data requests.

The Annual Data Report Committee (ADRC) reviews the data in previous ADRs, proposals for future editions, and ideas for expanded data availability on the USRDS website.

The Information Systems Committee (ISC) reviews hardware requirements, systems configuration, documentation, and performance, and evaluates technologies that may enhance database structure, function, and management.

The Special Studies Review and Implementation Committee (SSRIC) serves as the operations committee for SSC proposals and support of CC projects. It is a collaboration of CMS, the ESRD networks, and the providers.

The Data Request Review Committee (DRRC) reviews data requests requiring more than two hours of staff time to fulfill, and makes recommendations to the Project Officers based on the types of data sets requested and the ways in which the CC can improve the availability of data.

The Renal Community Council (RCC), with 30 professional, scientific, and advocacy groups, serves as a significant liaison between the USRDS and the ESRD community.

Reading the maps

The majority of disease mapping within this atlas is by Health Service Area (HSA), a group of counties described by the authors of the CDC Atlas of United States Mortality as "an area that is relatively self-contained with respect to hospital care."

Maps throughout the ADR present data divided into quintiles. Each data range in a legend contains approximately one-fifth of the data points included in the map. In the sample map here, for example, one-fifth of all data points displayed have a value of 10.8 or above.

To facilitate comparisons of maps that present data for several different years or time periods, we have applied a single legend to each map in a series, e.g., rates of diabetes in 1990 and 2000. Because such a legend applies to multiple maps, the data in each individual map are not evenly distributed in quintiles, and a map for a single year may not contain all the colors or ranges listed in the legend.

In the legends the numbers in parentheses indicate the mean values of the data points in the highest and lowest quintiles. These can be used to calculate the percent variation between these quintiles. For maps with shared legends we have provided these values by repeating the legends and inserting the unique quintile values.

On the summary page at the end of each chapter we have included several numbers to help you interpret the maps and their relation to other data presented in the ADR. The map-specific mean is calculated using only the population whose data are included in the map itself—i.e., the mean for a state map excludes all patients whose state of residency is unknown. This mean will usually not match data presented in tables elsewhere in the ADR, and should be quoted with caution. The overall mean includes all patients for whom data is available, whether or not their residency is known. We also include the number of patients excluded in the map-specific mean, and the total number of patients used for the overall calculation.

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We welcome feedback on all USRDS work, and all comments are reviewed by the Director, Deputy Director, and staff in order to improve future materials and ensure a strong working relationship between the USRDS and clinicians, researchers, patients, and others involved in ESRD care.